

641—154.73(124E) Reporting requirements.

154.73(1) Reporting test results. The laboratory shall generate a certificate of analysis for each primary sample that it tests and make the certificate of analysis available to the manufacturer who ordered the tests and the department through the department's secure sales and inventory tracking system, if available, or another laboratory information management system.

154.73(2) Tentatively identified analytes. A laboratory shall report on the certificate of analysis any tentatively identified analytes detected during the analysis of the primary sample. When a laboratory identifies additional analytes in a primary sample, the laboratory shall:

- a. Notify the department of the additional analytes detected.
- b. Refrain from issuing a final certificate of analysis to a manufacturer until given approval to do so by the department.

154.73(3) Additional reporting requirements.

a. In addition to the requirements described in rule 641—154.72(124E), the certificate of analysis shall contain, at a minimum, the following information:

- (1) All requirements of Standard ISO/IEC 17025;
- (2) Date of primary sample collection;
- (3) Date the primary sample was received by the laboratory;
- (4) Date of each analysis;
- (5) The LOQ and action level for each analyte, as applicable;
- (6) Whether the primary sample and lot passed or failed laboratory testing; and
- (7) A signature by the laboratory quality officer and the date the certificate of analysis was validated as being accurate by the laboratory quality officer.

b. Any test result that is not covered under the laboratory's ISO/IEC 17025 scope of accreditation shall be clearly identified on the certificate of analysis.

c. Measurements below a method's limit of detection shall be reported as "<" (less than) or "not detected" and reference the reportable limit. The reporting of zero concentration is not permitted.

d. Measurements \geq LOD but $<$ LOQ shall be reported as "detected but not quantified."

e. The number of significant figures reported shall reflect the precision of the analysis.

[ARC 3836C, IAB 6/6/18, effective 7/11/18]